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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,510	10/29/2003	Jeffrey J. Spiegelman	006357.00002	5029
30750	7590	02/23/2007	EXAMINER	
BANNER & WITCOFF, LTD. ATTORNEYS FOR CLIENT NO. 006357 28 STATE STREET 28TH FLOOR BOSTON, MA 02109			BRANDT, ADAM CURTIS	
			ART UNIT	PAPER NUMBER
			3771	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/696,510	SPIEGELMAN ET AL.
	Examiner Adam Brandt	Art Unit 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 November 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-57 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-27,30,31 and 35-57 is/are rejected.
- 7) Claim(s) 28,29 and 32-34 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/19/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Reissue Applications*

1. The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414.

The Applicant has set forth that the patent only contained method claims and that they wish to now claim method and apparatus claims. No specific error has been recited. The current error statement is confusing because method claims already exist and presently more method claims are added. Please identify the error in a new error statement, such as what subject matter was narrowly claimed and how is it being broadened.

### *Specification*

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because it exceeds the maximum of 150 words. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: reference number 53 is used when referring to a line and is then later used to reference a bag. Appropriate correction is required.

***Claim Objections***

5. Claims 46, 48, 49, 50, 51, and 52 are objected to because of the following informalities: Elements of the claims have reference numerals that do not exist in the drawing. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what “a process unit” is referring to. Claims 36-42 are rejected because they are dependent from claim 35, thereby rendering claims 36-42 indefinite.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (US 5,545,396) in view of Cates Jr. et al. (US 5,809,801).

Albert et al. (referred to as Albert hereafter) discloses a method of recovery and purification of a gas used to enhance a medical process which comprises; passing said gas to said medical process and therein using said gas for enhancement of said process, use in said process

also causing gaseous or liquid contaminants including water vapor, carbon dioxide, oxygen or nitrogen to become incorporated into said gas (column 12, lines 44-55; contact with other components contaminates gas); collecting at least a portion of thus-contaminated gas (column 13, lines 3-6); collecting said gas after such decontamination for recycle to said medical process and subsequent reuse therein (Albert acknowledges the need for recycling because of the cost of the noble and it is inherent that after the gas has been cleaned that it can be reused for the medical process.)

Albert does not disclose that it would determine which said gaseous or liquid contaminants are contained in said gas. It is inherent that if the gas is contaminated, then there is another substance other than the pure gas that was initially administered. Therefore, it would have been obvious to one of ordinary skill in the art to add a gas identification device in order to identify the contaminant gasses that are now mixed with the collected noble gas for the reason of recognizing what gasses need to be removed. Such a device is well known in the art.

Albert does not disclose a method step for drying said contaminated gas to reduce water concentration in the gas to not greater than 10 ppm. Albert does disclose that the gas can be captured for cleansing purposes. Cates Jr. et al. discloses a Hyperpolarized noble gas recovery apparatus the utilizes a gas purifier (Getter) to remove trace impurities, such as water vapor from the gas (column 11, lines 23-24). Therefore, it would have been obvious to one of ordinary skill in the art the time the invention was made to have modified Albert's method of recovery of noble gases with Cates. Jr. et al.'s gas purifier in order to reduce the moisture in the gas so that it will be easier to transport. It would have been obvious to filter the gas to an acceptable water

concentration such as 10 ppm in order prepare the gas for processing through the getters to remove other contaminants.

Albert discloses that noble gas is relatively expensive in regards to other gasses and it would be cost effective to filter out known contaminants such as carbon dioxide, oxygen, nitrogen or other gasses (column 12, lines 56-61). Albert discloses that zirconium getters are well known in the art (column 12, lines 63-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure Albert's getter to particularly filter carbon dioxide, oxygen, nitrogen, or other gasses to an acceptable concentration. Notice that the feature of choosing a particular concentration ie. 10 ppm or 1 ppm is considered as an obvious design choice because a filter/getter can be constructed to trap any level of contaminants. Cates Jr. et al. discloses several examples of getters for that are known to remove various gasses (column 14, lines 38-65).

As to claim 2-7 and 14, Albert discloses the gas is an isotope of Helium (abstract). Additionally, it would be obvious to one of ordinary skill in the art at the time the invention was made to configure the getters and to remove any gas components not needed thereby leaving the appropriate purified gas.

As to claims 8-13, the modified Albert's device has the necessary getter to remove water or other contaminants from the gas mix (column 13, lines 23-24; column 14, lines 54-65; column 16, lines 59 to 67). Any concentration can be adapted by modifying the getter accordingly.

As to claim 15, Albert discloses the noble gas is hyperpolarized and administered prior to the medical process (abstract).

As to claim 16, Albert discloses that the gas prior to hyperpolarization is under superatmospheric pressure since it is inherent that if the gas is stored, it is stored in a pressure vessel at pressure above atmospheric.

As to claim 17-21, Albert discloses that the medical procedure is medical imaging using hyperpolarized gas using helium-3 and/or Xenon-129 (Abstract).

12. Claims 22-27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert in view of Cates Jr. et al. as applied to claim 15 above, and further in view of Rosen et al. (6,085,743).

As to claim 22, Albert discloses said gas following hyperpolarization is collected if a first gas-tight container (11) which said gas is inhaled by patient during said medical imaging process and the exhaled into a second container (column 12, lines 1-3). The gas being exhaled is inherently contaminated gas. The gas from the container can then be drawn subatmospherically to the recovery apparatus. The modified Albert's device fails to disclose that the gas is removed from the second container at subatmospheric pressure. Rosen et al. teaches that it well known in the art to use a turbomolecular pump (26) to create a vacuum which creates subatmospheric pressure. Therefore, it would have been obvious to one of ordinary skill in the art the time the

invention was made to use the vacuum techniques of Rosen et al. with the noble gas recovery system of Albert in order to avoid depolarized the hyperpolarized noble gas.

As to claim 23, 24, 26, 27, Albert discloses that it is well known to store the gas under superatmospheric pressure (column 13, lines 1-6) which pertains to before and after the medical process.

As to claim 25, Rosen et al. discloses that it is well known to use vacuum techniques to move gas from one location to another.

As to claim 30 and 31, Rosen et al. discloses that it is well known in the art to use microprocessor to control a noble gas system (column 2, lines 29-22).

### ***Double Patenting***

13. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

14. Claims 43-55 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of prior U.S. Patent No. 6,471,747. This is a double patenting rejection.

Claims 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55 of the present application are identical to claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 of US patent 6,471,747.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 56 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 15 of U.S. Patent No. 6,471,747. Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent 6,471,747 discloses the claimed invention except that it details the location of the device in relation to that of the MRI machine. The present application does not disclose location of the device in relation the MRI machine. It would have been obvious to having ordinary skill in the art at the time the invention was made to place the gas recycling device at a gas outlet or anywhere near the MRI device that gas could be captured, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

***Allowable Subject Matter***

17. Claims 28, 29 and 32-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Henrich et al. (4,844,715); Rosen et al. (6,085,743); Zollinger et al. (2001/0029739); 6,427,452; 6,543,236; 6,237,363); Venkatesh et al. (6,471,747); Pines et al. (2005/0030026); Sato (6,963,199); Hasson et al. (6,269,648) are all related to the noble gas purification and recovery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ACB  
ACB

*Adam Brandt*  
Adam Brandt  
Examiner  
Art Unit 3771

*Justine Y.*  
JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

2/16/07